SEP - 5 2003

K032589

Summary of Safety Information *Premarket Notification, Section 510(k)*	**NOVARE SURGICAL SYSTEMS, INC.** **AUGUST 16, 2003**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Name: ENclose™ II Anastomosis Assist Device

Common Name(s): Vascular Clamp

Classification Name(s): Vascular Clamp

Manufacturer:
Name: Novare Surgical Systems, Inc.
Reg. Number: 2954739
Address: 10231 Bubb Road
Cupertino, CA 95014
Classification(s):

Sec. 870.4450 Vascular clamp. (a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily. (b) Classification. Class II (performance standards).

Device Class: Class II for the requested indications
Classification Panel: Cardiovascular Devices Panel
Product Code(s): DXC

Equivalent Predicate Device:
The ENclose™ Anastomosis Assist Device is substantially equivalent to the following legally marketed vascular clamp(s):

Includer™ Vascular Clamp - Novare Surgical Systems, Inc., K010694
Includer™ (ENclose™) Vascular Clamp - Novare Surgical Systems, Inc., K023682

Sec. 870.4450 Vascular clamp. (a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily. (b) Classification. Class II (performance standards).

Device Class: Class II
Product Code(s): DXC

The new anastomosis device is essentially identical to the previous device. Equivalency can be seen with respect to place of manufacture, physical appearance, functional testing, material certification, surgical technique and indications for use. A feature comparison chart follows this section.

FEATURE	ENclose™ II Anastomosis Assist Device	Includer™ / ENclose™	SE?
Indications for Use:	The ENclose™ II Anastomosis Assist Device is intended for use by cardiac surgeons in place of partial occluding clamps during coronary artery bypass grafting (CABG) procedures requiring one to three proximal anastomoses in ascending aortas free of atheromatous disease.	Identical	YES
Materials:	Medical grade plastic, stainless steel and silicone	Identical	YES
Design:	Clamp	Identical	YES
Sterilization:	Radiation (e-beam)	Identical	YES
Manufacturer:	Novare Surgical Systems, Inc.	Identical	YES
Product Code:	DXC	Identical	YES
K - Number:	Pending	K010694, K023682	YES

The proposed changes do not represent a significant or deleterious change to the device. Substantial equivalence is based on all physical and clinical attributes of the device being indistinguishable from the cleared device, including, place of manufacture, physical appearance, though slightly different in color and size, has not affected the performance requirements, functional elements, material certification, surgical technique nor indications for use.

Device Description:
General description of the change(s). The proposed changes are limited to manufacturing/processing changes, a change in the colorant used in the existing plastic of the body of the device, a change in the shape of the expandable region of the lower jaw and the addition of a fiber reinforced polymer hex driver to assist with deployment of the device if desired. The current FDA cleared indications granted for single and up to three anastomosis procedures remains unchanged.

The modified ENclose™ II Anastomosis Assist Device is an intraoperative device used to assist in the creation of one to three proximal anastomosis sites in the execution of coronary artery bypass grafting (CABG) procedures. Materials for the new device are identical to the previous device with the exception of the colorant.

Company Contact:
Mr. Kerry Pope
Novare Surgical Systems, Inc.
10231 Bubb Road
Cupertino, CA 95014
408.873.3161

Submission Correspondent:
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

Special Controls:
FDA published special controls. The following special controls are believed to apply to the marketing of class II devices:

(i) Compliance with material standards,
(ii) Compliance with biocompatability standard, and
(iii) Compliance with specified labeling requirements.

Novare Surgical Systems, Inc. also meets appropriate general controls authorized under Sections 501, 502, 510, 516, 518, 519, and 520 of the Food, Drug, and Cosmetic Act.

Sterility Processing:
The ENclose™ II Anastomosis Assist Device is provided sterile and is designed strictly for single patient use. The device may not be cleaned, reprocessed or reused under any circumstances. The product must be handled, stored and placed into use in such a way that it is protected from inadvertent damage or contamination. When used, the product must be placed into use following accepted surgical sterile technique.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 2003

Novare Surgical Systems, Inc.
c/o David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane
Suite C-100
Pleasant Hill, CA 94523

Re: K032589
Enclose II Anastomosis Assist Device
Regulation Number: 21 CFR 870.4450
Regulation Name:
Regulatory Class: Class II
Product Code: DXC
Dated: August 16, 2003
Received: August 22, 2003

Dear Mr. Schlerf:

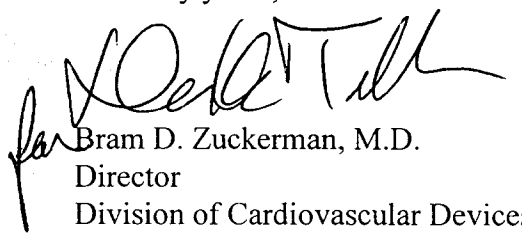
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number : K032589

Device Name(s): ENclose™ II Anastomosis Assist Device

Indications for Use Statement(s):

The ENclose™ II Anastomosis Assist Device is intended for use by cardiac surgeons in place of partial occluding clamps during coronary artery bypass grafting (CABG) procedures requiring one to three proximal anastomoses in ascending aortas free of atheromatous disease.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032589

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)